

P-19-0025

Chemical Name: 11-Docosene

CASRN: 62978-77-2

ASSIGNMENTS	NAME	DATE
SAT Chair	Rebecca Daiss	SAT Date 11/30/18
HH Hazard Assessor (A)	Keith Jacobs	SAT Date 11/30/18
HH Hazard QC Reviewer (A)	Gino Scarano	12/05/18
HH Risk Assessor FOCUS (B)	Maggie Johnson	12/27/18
HH Risk QC Reviewer (B)	Sharon Oxendine	12/26/18

Human Health Report Status:		DATE COMPLETED
X	HAZARD DRAFT- Pending Review	11/30/18
X	HAZARD REVIEWED	12/05/18
X	HAZARD FINAL	12/14/18
X	RISK DRAFT- pending review	12/26/18
X	RISK REVIEWED	12/26/18
X	RISK-FOCUS FINAL- Uploaded	12/28/18
	POST-FOCUS UPDATE DRAFT	
	POST-FOCUS UPDATE FINAL- Uploaded	

1 HUMAN HEALTH SUMMARY

EPA estimated the human health hazard of this chemical substance based on its estimated physical/chemical properties, by comparing it to structurally analogous chemical substances for which there are data on human health hazard and other structural information.

Based on the hazard determination and available quantitative risk information, EPA concludes that there is risk for the PMN substance.

1.1 Hazard Summary

1.1.1 Absorption / Metabolism

Absorption is poor to nil all routes physical/chemical properties.

1.1.2 Structural Alerts

None

1.1.3 Hazard Concerns

- Based on OECD SIDS HPV document (2004) the weight of the evidence indicates branched and linear alkenes (C6-C24) have a similar low level of mammalian toxicity and the toxicity profile is not affected by changes in the location of the double bond or the addition of branching to the structure.
- Concern for hydrocarbon pneumonia based on analogues.
- Concern for liver or systemic toxicity based on data from C20-24 internal olefins.

1.1.4 Hazard Summary (narrative)

EPA estimated the human health hazard of this chemical substance based on its estimated physical/chemical properties, by comparing it to structurally analogous chemical substances for which there are data on human health hazard and other structural information.

Absorption is poor to nil all routes based on physical/chemical properties. Hydrocarbon pneumonia hazard identified based on analogues. Liver or systemic toxicity hazard identified based on data from C20-24 internal olefins. EPA quantitatively assessed the PMN substance using analogue data. A NOAEL of 100 mg/kg-day was identified as the POD for liver and systemic toxicity. This POD was used to derive exposure route- and population-specific points of departure for quantitative risk assessment of the PMN substance. A benchmark MOE of 100 was identified to account for interspecies and intraspecies uncertainty/variability.

1.2 Exposure and Risk Summary

For this assessment, EPA assessed worker exposure via dermal exposure and general population via ingestion. Consumer exposures were not assessed because consumer uses were not identified as conditions of use.

1.2.1 Workers

Risks were identified for workers liver or systemic toxicity via dermal exposure based on quantitative hazard data for an analog (MOE = 24 benchmark \geq 100). Inhalation exposures are negligible based on low vapor pressure (VP < 0.001 torr) and no mist generated.



1.2.2 General Population

Risks were not identified for the general population for liver or systemic toxicity via ingestion of drinking water ($MOE_{Adult} = 4,400$; $MOE_{Infant} = 1,000$; benchmark $MOE = 100$) or fish ($MOE = 2,500$; benchmark $MOE = 100$).

1.2.3 Consumers

Risks to consumers were not evaluated because consumer use was not identified as a condition of use.

1.3 Assumptions and Uncertainties

Absorption of the PMN is based on physical/chemical properties

Aspiration hazard is only relevant if the PMN substance exists as a liquid

There are no measured data on the PMN substance itself.

1.4 Potentially Useful Information

Potentially useful information would inform understanding of:

Pulmonary toxicity/aspiration hazard and specific target organ toxicity

2 HUMAN HEALTH HAZARD

2.1 Chemistry Summary

PMN:	Submitter		CRSS Date:
P-19-0025	Bercen, Inc.		Nov 29, 2018
Max. PV (Kg):	Binding Option Marked:	Manu.	Import
	false	X	
MW:	% <500:	% <1000:	CASNO:
308.60			62978-77-2
Structure:			
	Meas.	Est.	
	MP	<20	
	BP	361	
	Pres.		
	VP		
	S-H2O	<0.000001	
	Log P		
Chemical Name:	Analog:		
11-Docosene			
Use:			

2.1 SAT Summary

2.1.1 Absorption

Absorption is poor to nil all routes physical/chemical properties.

2.1.2 SAT Health Summary

Based on OECD SIDS HPV document (2004) the weight of the evidence indicates branched and linear alkenes (C6-C24) have a similar low level of mammalian toxicity and the toxicity profile is

[REDACTED]

not affected by changes in the location of the double bond or the addition of branching to the structure. There is concern for hydrocarbon pneumonia.

2.1.3 Exposure Routes of Interest

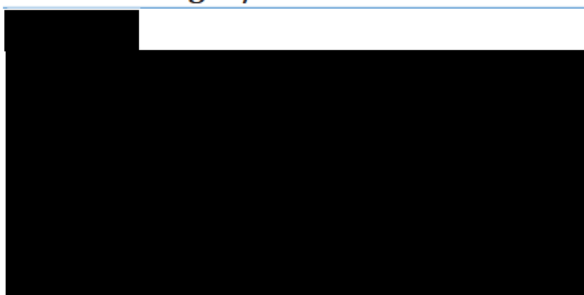
Route of Interest	
X	Inhalation:
X	Dermal:
X	Ingestion:

2.2 Toxicity Data

2.2.1 PMN Data

None

2.2.2 Analogue/Metabolite Data



OECD SIDS SIAM 19, 2004 - Higher olefins (C6-C24 Alkenes)

- Overall low toxicity
- In females, NOELs => 100 mg/kg from C20-24 internal olefins (internal double bond) based on hepatocyte hypertrophy and increased liver weight
 - Also data demonstrating changes in clinical chemistry/hematology and organ/body weights
 - Specific study details not provided, only an overview of the available data provided
- Only mild potential for skin/eye irritation at high concentrations and prolonged exposure
- Not skin sensitizers



SAT Health Summary

Expect poor absorption via all routes (pchem). Concern for lung effects (chemical pneumonia) if inhaled.

2.2.3 SDS Data

May cause respiratory irritation.

ACUTE TOXICITY	Rat, LD 50: > 5,000 mg/kg
Oral:	Expected to be of low toxicity
Dermal:	LD 50: > 5,000 mg/kg
	Expected to be of low toxicity:
Inhalation:	Low toxicity by inhalation
CARCINOGENICITY:	The product is not a recognized carcinogen.
MUTAGENICITY:	Tests on bacterial or mammalian cell cultures did not show mutagenic effects.
TERATOGENICITY:	Not established
REPRODUCTIVE TOXICITY	Rat (male and female), Oral Dose once daily: 0, 100, 500, or 1000 mg/kg
General Systemic Toxicity:	OECD Guideline 421, NOAEL f1: 1.000 mg/kg

2.2.4 Other Information

None

2.3 Human Health Category (From US EPA 2010 document)

Chemical Category: N/A

Chemical Category Health Concerns: N/A

Category Testing Strategy: N/A

2.4 Point of Departure Selected and Basis

2.4.1 POD for Higher Olefins (Oral)

POD type: NOAEL

POD Value: 100 mg/kg

POD Chemical: Higher olefins (C20-24 internal olefins with internal double bond) - data summarized group of similar olefins

POD Route: Oral

POD Hazard Endpoint: Liver or systemic toxicity

POD Basis: In females, NOELs => 100 mg/kg from C20-24 internal olefins (internal double bond) based on hepatocyte hypertrophy and increased liver weight. There is also data demonstrating changes in clinical chemistry/hematology and organ/body weights. The OECD SIDS document concludes that higher olefins exhibit overall low toxicity, however these effects suggest potential liver or systemic toxicity at 100 mg/kg or higher.

POD Benchmark MOE: 100 (10X interspecies UF and 10X intraspecies UF)

Reference: OECD SIDS SIAM 19, 2004

3 HUMAN HEALTH RISK

3.1 USES and EXPOSURES

3.1.1 Uses

3.1.2 Worker Exposure

Workers can be exposed to the PMN via dermal contact during Manufacturing and Use as

3.1.2.1 Inhalation

Manufacturing:

- Inhalation negligible (VP < 0.001 torr) and not used in any way that would generate a mist.

Use:

- Inhalation negligible (VP < 0.001 torr) and not used in any way that would generate a mist.

3.1.2.2 Dermal

Manufacturing

Loading Liquid Product into Tank Trucks

Exposure to Liquid at 100% concentration

- High End Potential Dose Rate: **2.2E+3 mg/day** over 100 days/yr

Use:

Unloading Liquid Product from Containers

Exposure to Liquid at 100% concentration

- High End Potential Dose Rate: 2.2E+3 mg/day over 250 days/yr

3.1.3 General Population Exposure:

3.1.3.1 Drinking Water

Drinking water ingestion adult ADR 1.63e-2 mg/kg/day and LADD 2.71e-4 mg/kg/day

3.1.3.2 Fish

Fish ingestion ADR 2.80e-2 mg/kg/day

3.1.3.3 Ground Water Ingestion via Landfill Leachate

Not assessed based on negligible migration to ground water (per Fate Report).

3.1.3.4 Air/Inhalation

Exposure from predicted environmental stack incineration releases was not assessed for the acute and chronic scenarios, as they are expected to be negligible.

3.1.4 Consumer Exposure

No identified consumer uses or exposures.

3.2 RISK CALCULATIONS

3.2.1 Worker Calculations

Risk for workers for liver or systemic toxicity via dermal exposure were identified (MOE = 24; benchmark ≥ 100). Inhalation exposures are negligible based on low vapor pressure (VP < 0.001 torr) and no mist generated.

Worker MOE Calculations using Oral NOAEL of 100 mg/kg-bw/day for Higher olefins (C20-24 olefins with internal double bond) based on Liver or systemic toxicity; absorption adjustment of 15% (poor); and Engineering Report PDR. Benchmark MOE ≥ 100												
	Animal or Human			Human							Benchmark MOE	Endpoint Type
Exposure Route	POD mg/kg-bw/day	POD Exposure Duration Days/Wk	POD Route % Absorp	Exposure mg/day Potential Dose Rate (PDR)	Exposure Duration Days/Wk	Exposure Route % Absorp	Body Weight kg	Exposure mg/kg-bw/day	Structural Alert as % of PMN	Margin of Exposure (MOE)	100	NOAEL
Dermal	1.0E+02	5	100%	2.2E+03	5	15%	80	2.8E+01	100%	24.2		

3.2.2 General Population Calculations

Risk for liver or systemic toxicity was not identified for the general population exposed via ingestion of drinking water (MOE_{Adult} = 4,400; MOE_{Infant} = 1,000; benchmark MOE = 100) or fish (MOE = >2,500; benchmark MOE = 100).

Population MOE Calculations using Oral NOAEL of 100 mg/kg-bw/day for Higher olefins (C20-24 olefins with internal double bond) based on Liver or systemic toxicity and Exposure Report PDRs. Benchmark MOE = 100									
	Animal or Human			Human					
Exposure Route	POD mg/kg-day	POD Exposure Duration Days/Wk	POD Route % Absorp	Exposure mg/kg-day Acute Dose Rate (ADR)	Exposure Duration Days/Wk	Exposure Route % Absorp	Multiplier for Susceptible Subpopulations	Structural Alert as % of PMN	MOE (Benchmark MOE ≥ 100)
Drinking Water (adult)	1.0E+02	5	100%	1.6E-02	7	100%	1.0	100%	4,382
Drinking Water (infant)	1.0E+02	5	100%	1.6E-02	7	100%	4.2	100%	1,043
Fish Ingestion	1.0E+02	5	100%	2.8E-02	7	100%	1.0	100%	2,551

3.2.3

Consumer Calculations

Risks to consumers were not evaluated because consumer use was not identified as a condition of use.